

The Examiner rejected the claims under 35 U.S.C. § 112 ¶ 2 and 35 U.S.C. § 102. Applicant respectfully requests withdrawal of these rejections for the following reasons.

The Section 112 rejection was based on the presence of a number of technical flaws in the claim language. The claims have been redrafted as set forth above to correct those technical flaws. The Specification has also been clarified. No diminution of the scope of the Specification or the claims should be inferred from these technical corrections. It is not believed that the amendments to the Specification comprise new matter. The changes to the Specification were intended to adapt this application, originally filed in Germany, to reflect U.S. patent practice.

Ed, DO I need to have the priority document in German to translate in English - proof of no new matter,

The Examiner's attention is drawn to the change on Page 2, paragraph 1, where the term "comprising" has been inserted for the term "consisting of," when referring to the scope of the process of the invention. The German language version of this phrase is found on Page 2, lines 11-12 of the PCT application. The language is:

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"Gegenstand der Erfindung ist also ein Verfahren zur Herstellung Arzneimittel enthaltender Brausezubereitungen aus"

The verb "enthaltender" was translated as "consisting of." This translation, however, does not reflect the legal usage of the term "consisting of" in U.S. patent law. Enclosed with this Amendment are copies of pertinent entries in Langenscheidt's and

Cassell's German-English dictionaries. These entries show the definitions of "enthaltender" and "bestehen auf" in English and the definitions of "comprising" and "consisting" in German. The better translation of "enthaltender" is "comprising." The better translation of "consisting of" is "bestehen auf." Since the verb "enthaltender" was used in the original German, correction of the application from "consisting of" to "comprising" does not comprise new matter.

The claimed invention is directed to effervescent compositions with improved stability. These compositions are prepared in accordance with the claimed methods. Applicant has discovered that product stability is improved by incorporating at least one member of the effervescent couple in a dispersion of a fusible sugar, sugar alcohol or sugar substitute. The compositions of the claimed invention, therefore, comprise an effervescent system of a CO₂ donor and an acidic component. The compositions further comprise a pharmaceutically active substance, and an ancillary substance. The ancillary substance comprises at least one ingredient selected from the group consisting of fusible sugars, sugar alcohols, and sugar substitutes. Either the CO₂ donor or the acidic component (or both) is dispersed in the fusible sugar, sugar alcohol, or sugar substitute.

The Examiner has rejected the claims under 35 U.S.C. § 102 (b), based on UK Patent No. 2,307,857 to Leslie et al. ("Leslie").

Leslie is directed to an effervescent composition containing tramadol, an analgesic with an unpleasant taste. Leslie reports that “[w]e have surprisingly found that a formulation containing tramadol or pharmaceutically acceptable salt thereof and an acid/base couple, when dissolved in an appropriate amount of water, is of surprisingly acceptable palatability with an unexpectedly low degree of bitterness even in the absence of sweeteners.” (Page 2, lines 24-28.) Leslie concerns itself only with flavor. Stability is not the objective of Leslie, and Leslie concedes that any “conventional” method may be used to make its tramadol product, including a process in which the “tramadol . . . and the components of the acid base couple may be simply dry mixed and compressed to form tablets.” (Page 2, lines 30-32.) In a preferred process, polyethylene glycol is added as a binder, and Leslie’s materials are blended in via mechanical action at an elevated temperature.

Since Leslie is not concerned with stability, Leslie does not recognize that one or more components of an effervescent couple may be dispersed in a fusible sugar, sugar alcohol or sugar substitute. Indeed, Leslie uses very low, or even no, amounts of sweetener in its examples. The highest amount of sweetener actually used in Leslie is 5 mg or 0.22 weight percent of the formulation (Example 1). This amount of sweetener is matched with 990 mg of citric acid (43.27 weight percent of the formulation) and 1,243 mg carbonate (54.33 weight percent). Nobody would describe the citric acid or the carbonate as being “dispersed” in the sweetener, especially since example 1 physically mixes all the ingredients and feeds them to a tablet press.

Since the instant application is only for method of making (process claim) Appl's argument is irrelevant on stability

Since Appl. does not claim the amount of sugar so the prior art reads on Appl's 'instant claim'.

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Example 3, the example cited by the Examiner, does not teach or suggest the claimed invention. Saccharin comprises only 0.2 weight percent of the formulation, while the citric acid comprises 39 weight percent of the formulation and the carbonates comprise 49 weight percent of the formulation. Leslie cannot teach or suggest dispersion of one or both parts of an effervescent couple in a fusible sugar, sugar alcohol or sugar substitute simply because Leslie does not have enough sugar substitute to form a dispersion. Instead, Leslie relies on polyethylene glycol to act as a binder.

In view of the arguments set forth above and the claim amendments presented herein, Applicants respectfully submit that the pending claims are in condition for allowance. Reconsideration is respectfully requested. The Examiner is invited to call the undersigned attorney at 973 408-8229.

Respectfully Submitted,



Richard S. Bullitt
Reg. No. 30,733

Bayer Corporation
36 Columbia Road
Morristown, NJ 07962